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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,716	09/29/2003	Donald R. Ricci	213202.00483	9274

27160 7590 08/23/2007
PATENT ADMINISTRATOR
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,716

Applicant(s)

RICCI, DONALD R.

Examiner

Quynh-Nhu H. Vu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28, 30, 31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28, 30-31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/02/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/29/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION***Claim Rejections - 35 USC § 112***

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "a guide wire branch; and an inflation branched angled with respect to said guide wire branch" of claim 45 do not disclose anywhere in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 30-31, 33-34, 37 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Gharibadeh et al. (US 5,458,613).

Gharibadel discloses a balloon dilation catheter comprising: a guide catheter10, a tubular member 11 having a proximal end and a distal end; an inflatable balloon 13 disposed at the distal end of the tubular member; a first lumen 12 disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen 14, 20 disposed in the tubular member for receiving a guide wire 31, the second lumen having a first opening and a second opening at the distal end of the tubular member; a first slits (24, 26) disposed on tubular member; an adapter (33, 35) disposed at the proximal end of the tubular member; and an adapter slit (38, 39) disposed in the adapter; Fig. 3 clearly shows the slit to be narrow than the

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an outside diameter of the guide wire and Fig. 2 clearly shows the adapter slit being straight from a proximal end of the catheter to a distal end of the adapter; a third lumen is considered to be element 42 and a stiffening member considered to be the guide-wire 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh et al. (US 5,458,613) in view of Schiffer (US 5,195,978).

Gharibadel discloses the invention substantially as claimed. See above. Gharibadel does not clearly disclose the first slit extends from the first opening to an area on the tubular member extends from the first opening to a second opening wherein the second opening is proximal to the inflatable balloon

Schiffer discloses a slit 32 extends from the first opening (located proximal 24) to the second opening (located distal end 26) (Figs. 1-3); wherein the second opening is proximal to the inflatable balloon.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Gharibadel with the slit, as taught by Schiffer, in order to allow the physician to progressively expose and remove the guide wire from lumen in a simple and expeditious manner.

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Regarding claim 35, Gharibadel in view of Schiffer disclose the invention substantially as claimed. See above. Gharibadeh discloses a radio opaque marker 40 on a tubular extension 20. However, they do not disclose a radiopaque marker on the tubular member 11. It is common knowledge in the prior art to place radiopaque markers on tubs in the analogous art of balloon catheters for the purpose of tracking the location of the specific sections of the catheter in the body.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadel as applied to claim 25 above, and further in view of Horzewski et al. (US 4,748,982).

Gharibadel discloses the invention substantially as claimed. See above. Gharibadel in view of Schiffer do not disclose; the tubular member having various densities to provide a decreasing stiffness from the proximal end to the distal end.

Horzewski discloses that the tubular member 12 having various densities to provide a decreasing stiffness from the proximal end to the distal end (col. 2, lines 30-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by Horzewski, in order to achieve the desirable stiffness for the shaft.

Additionally, Horzewski also discloses the radio-opaque marker 27, 28 disposed on the tubular member 12.

Claims 38-41 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadel as applied to claims 30-31, 33-34, 37 above, and in view of Barry (US 5,685,847).

Gharibadel discloses the invention substantially as claimed. See rejection of claim 25 above. Gharibadeh do not disclose a stent mounted on the balloon. Barry teaches a balloon

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catheter for deploying a stent. It is well known in the art to use balloon catheter to deliver stents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh, as taught by Barry, in order to deploy stents.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadel in view of Barry as applied to claims 38-39 above, and further in view of Horzewski et al. (US 4,748,982).

Similarly to rejection of claim 36, Gharibadel in view of Barry discloses the invention substantially as claimed. See above. Gharibadel in view of Barry do not disclose the tubular member having various densities to provide a decreasing stiffness from the proximal end to the distal end.

Horzewski discloses that the tubular member 12 having various densities to provide a decreasing stiffness from the proximal end to the distal end (col. 2, lines 30-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh in view of Barry, as taught by Horzewski, in order to achieve the desirable stiffness for the shaft.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QNV



LOAN H. THANH
PRIMARY EXAMINER